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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,697	12/22/2003	Peter Kufer	DEBE:028US	5635

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,697	KUFER ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/26/04*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. The following is noted:

Claims 15, 19, 39 and 43 encompass 8 different effector antigens while claims 20 and 44 encompass 56 different targeting antigens for the claimed bispecific antibodies. Bispecific antibodies as claimed differ with respect to their binding specificity based on their variable domains that bind specifically to the specific target antigen and the specific effector antigen on human effector cell, a person of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

II. Claims 1-57 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-448. Claims 15-24, 39-48, and 56-57, drawn to a specific bispecific antibody comprising two antibody variable domains on a single polypeptide chain, wherein a first portion of the bispecific antibody is capable of recruiting the activity of a human immune effector cell by specifically binding to an effector antigen located on the human immune effector cell, said first portion consisting of one antibody variable domain; and a second portion of the bispecific antibody is capable of specifically binding to a target antigen other than the effector antigen, and a kit comprising the specific bispecific antibody, classified in Class 530, subclass 387.3; Class 435, subclass 810.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Group 449. Claim 49, drawn to an isolated nucleic acid encoding SEQ ID NO: 1 or a nucleotide sequence exhibiting at least 70% homology therewith and a kit comprising said nucleic acid, classified in Class 536, subclass 23.5.

Groups 450-898. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **proliferative disease** and a specific **tumor** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific proliferative disease or tumor using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 899-1347. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder**, and a specific **inflammatory disease** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific immunological disorder or inflammatory disease using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that

read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 1348-1796. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **autoimmune disease,** and a specific **immunological disorder** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific autoimmune disease or immunological disorder using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 1797-2245. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **infectious disease, and a specific viral disease** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific infectious disease or viral disease using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 2246-2694. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder** and a specific **allergic reaction** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific immunological disorder or allergic reaction using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 2695-3143. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **infectious disease** and a specific **parasitic disease** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific infectious disease or a specific parasitic disease using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination. This requirement extends to each of grouped sets of inventions below.

Groups 3144-3592. Claims 50-54, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder**, a **graft-versus-host and a host-versus-graft disease** in a subject comprising the step of administration of an effective amount of a specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, classified in Class 424, subclass 133.1.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of treating a specific immunological disorder such as graft-versus-host or host-versus-graft disease using a specific bispecific antibody that binds specifically to (1) a specific effector antigen on human immune effector cell such as the ones recited in claims 15, 16, 19, 39, 40, 43 and (2) a specific target antigen such as the ones recited in claims 20, 22, 23, 24, 44, 45, 46, 47 and 48. Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Group 3593. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **proliferative disease**, and a specific **tumor** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3594. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder** and a specific **inflammatory disease** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3595. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder**, and a specific **autoimmune disease** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector

antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3596. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **infectious disease** and a specific **viral disease** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3597. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder**, and a specific **allergic reaction** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3598. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **infectious disease**, and a specific **parasitic disease** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Group 3599. Claim 55, drawn to a method of prevention, treatment or amelioration of a specific **immunological disorder**, a **graft-versus-host disease** and a **host-versus-graft disease** in a subject comprising the step of administration of an effective amount of a **nucleotide sequence** encoding the specific bispecific antibody that specifically bind to a specific effector antigen located on the human immune effector cell, and a specific target antigen other than said effector antigen, Classified in Class 514, subclass 44.

Linking claims 1-14 and 25-38 will be examined along with Groups 1-448 if any one of said Groups is elected.

Claims 1-14 and 25-38 link inventions 1-448. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-14 and 25-38. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-449 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products such as bispecific antibody and nucleic acid as claimed differ with respect to its structure, binding specificity, and biochemical properties. Therefore, they are patentably distinct.

Inventions of Groups 1-448 and Groups 450-3592 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in treating different diseases that differ with respect to their etiology as claimed or materially different process such as binding assay. Therefore, they are patentably distinct.

Inventions of Group 449 and Groups 3593-3599 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in treating

different diseases that differ with respect to their etiology as claimed or materially different process such as making polypeptide. Therefore, they are patentably distinct.

IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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